UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,944	07/16/2001	John Ernest Hart	GJE-68	6466

23557 7590 05/13/2004

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,944	HART, JOHN ERNEST	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-6,8,11-15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *15 and 17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3-6,8 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I, (claims 1, 3-6, 8 and 11-14) in the paper(s) filed 11/06/2003 is acknowledged. The traversal is on the ground(s) that the unifying technical feature is a characterization that the claimed material is inducible by clomiphene and has the ability to reduce organ mass. This is not found persuasive because the material of the cited patent US 4,734,398 has the ability to reduce organ mass and it is isolated at the time of ovulation. Since clomiphene is an agent that is known to induce ovulation, thus, the materials circulating in animal plasma during ovulation are reasonably expected to be the same regardless the fact whether ovulation is normal or induced. Moreover, it is a known fact that weight loss and improvement in ovulation rates are related events at least for the obese patients. Furthermore, the cited patent US 4,734,398 teaches the material that has the same molecular weight as the claimed material and the cited patent US 4,734,398 teaches material that has been made by the same process as the claimed material. Thus, the special corresponding technical feature is known in the art as explained in the prior office action. Therefore, the unity of inventions is broken. The requirement is still deemed proper and is therefore made FINAL.

Claims 15 and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper(s) filed 11/06/2003.

Claims 1, 3-6, 8 and 11-14 are under examination in the instant office action.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 8 and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by US 4,734,398 or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,734,398.

Claims are directed to an endogenous material inducible in a mammal by clomiphene and having ability to reduce mass of body organs including non-gonadal organs, wherein the material is obtained by collecting an ovarian venous blood of female mammal, preparing plasma from the ovarian venous blood, partially purifying the material from the plasma to obtain fractions with molecular weights in the ranges 10-30 kD and/or 10-20 kD. Some claims are further drawn to the protocol of purifying the material centrifuging blood, using ion exchange chromatography eluted fractions with gradient of 0-0.3 M NaCl.

US 4,734,398 discloses a material having ability to reduce organ mass (col. 3, line 55-58 or col. 10, lines 47, 61-64), which is obtained from ovarian venous blood of human female patients including patients with regular menstrual cycles. Blood collection is done on days 12-14 after last menstrual period that is during ovulation (col. 8, line 61). The material is obtained by a

process comprising steps of collecting an ovarian venous blood of female mammal (col. 8, line 63-65), preparing plasma from the ovarian venous blood by centrifugation (col. 9, lines 8, 18-19), partially purifying the material from the plasma by dialyzing with 10 kD exclusion membrane (col. 9, line 26), by chromatography and by washing with 0.5 M NaCl solutions (col. 9, lines 8-31). The patent teaches obtaining fractions with molecular weights in the ranges within 1-30 kD and/or 10-20 kD such as 12-15 kD, 14-18 kD, 22-25 kD that have capability of reducing organ mass or ovarian weight (col. 4, lines 19-21 and lines 27-31, col. 11, lines 52-54).

Thus, the cited patent US 4,734,398 discloses material and composition with the material wherein the material and/or material fractions appear to be identical to the presently claimed material and/or its fractions since the cited material is obtained from identical source such as ovarian venous blood of a mammal as required for the claimed material, it is characterized by the same molecular weight as the claimed material and it produces identical effect such as organ mass reduction when administered to a patient as required for the claimed material. Furthermore, the material of the cited patent is collected about the time of ovulation during female monthly sexual cycle and, thus, the collected material it is considered to be the same material that would have been induced by clomiphene within the meaning of the instant claims since clomiphene is ovulation-inducing agent. The materials circulating in plasma during ovulation are reasonably expected to be the same regardless the fact whether ovulation is induced or it is normal at least with respect to the material as claimed and as disclosed. Consequently, the claimed invention is anticipated by the teaching of the cited patent US 4,734,398.

In the alternative, even if the claimed material and/or its fractions are not identical to the referenced material/fractions with regard to some unidentified characteristics such as related to

the protocol of purification including the use of a particular ion exchange chromatography columns or specific concentrations of NaCl, for example, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced material and/or fractions are likely to inherently possess the same characteristics of the claimed material particularly in view of the same characteristics which they have been shown to share such identical molecular weight, identical effects related to the weight reduction and identical source of isolation including time of isolation such as during ovulation. Thus the claimed would have been obvious to those skilled in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by US 4,734,398, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,734,398.

Claims 1, 3-5, 8 and 11-13 as explained above. Claims 6 and 14 are further drawn to the use of a sheep as source of mammalian ovarian venous blood for making claimed material.

US 4,734,398 is relied upon as explained above. The particular disclosure is related to human patients as source of mammalian ovarian venous blood for making materials of interest. Thus, the cited patent is lacking specific disclosure related to a sheep. However, the cited patent teaches that the disclosed material/fractions are proteins (col. 8, line 61 and col. 10, last line) and that the activity of the material is interspecies and that it is produced and effective for various mammals (col. 3, lines 29-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain the claimed material/fractions from various mammals including mammals such as human and sheep with a reasonable expectation of success in obtaining material/fractions having same effects as related to organ mass reduction and as related to ovulation or clomiphene-induced ovulation within the meaning of the claims because activity of same or similar proteins is interspecies and the same/similar proteins and effects are produced in various mammals as taught and/or suggested by the cited patent. One of skill in the art would have been motivated to use various mammals including sheep as the source of therapeutically valuable materials for the expected benefits in maximizing amounts of the collected materials. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented be the cited prior art. Therefore, the claims are properly rejected under 35 USC 103.

Response to Arguments

Applicant's arguments filed 11/06/2003 and 7/18/2003 have been fully considered but they are not persuasive.

The Declaration filed 7/18/203 and arguments based thereon have been fully considered however they are not persuasive because the disclosure of the declaration is confusing as to the significance of the differences that are claimed, that are argued and that are disclosed by the cited prior art.

Applicant argues that the instant patent application is related to a compound named "micrin". The "micrin" is a naturally occurring substance that it might also be induced by clomiphene (declaration page 1 at it. 5). Thus, the characteristics of the claimed compound such as being inducible by clomiphene does not appear to be a critical characteristic as argued in the paper(s) filed 11/06/2003 with respect to the claimed material as intended by the instant application. Applicant argues that the "FRP" compound that is disclosed by the cited patent US 4,734,398 (diZerega) is found in ovarian venous blood only and it would not be detectable in peripheral blood (declaration it.7-9). However, the claimed invention encompasses a material that is required to be isolated from ovarian venous blood of a mammal that is in the phase of ovulation or that is induced to ovulate by clomiphene. The cited material/fractions disclosed by US 4,734,398 (diZerega), whether named "FRP" or not, are made by the same method as required by the claimed invention. The applicant's material is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness for the product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Applicant appears to argue the differences in potential uses of the diZerega's FRP and of the applicant's "micrin" (declaration it. 10-12) such as contraception/infertility and general organ or tissue hypertrophy respectively. However, the fractions of the same molecular weight as required by the claimed invention are disclosed by the cited patent US 4,734,398 (diZerega) and these disclosed fractions are capable to reduce organ mass as demonstrated for the ovarian

weight reduction by the cited patent US 4,734,398 (diZerega). The applicant's claimed material is open to the weight reducing effects as related to any organ by the virtue of the open language "including" and, thus, the claim language includes ovarian organs. Although the disclosure by diZeraga's patent is silent about potential effects as related to a general organ weigh reduction, it teaches the same molecular weight fraction(s) obtained by the same method as required for the claimed invention wherein these fractions are clearly capable to reduce weight of at least one organ. Thus, the presently claimed material is anticipated by US 4,734,398 or, in the alternative, is obvious over US 4,734,398. Moreover, the applicant's material as intended is poorly characterized, for example: the nature and/or chemical structure of the intended "micrin" is not disclosed in the as-filed specification. Applicant has not demonstrated the link between structural characteristics of the applicant's material that is presently claimed and the potential functional effects that are argued.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicant's materials differ and, if so, to what extent, from the materials discussed in the prior art. Accordingly, it has been established that the prior art material/fractions that have the same molecular weights and produced by the same method as claimed, likewise share the property of being able to produce similar effects, and thus demonstrate a reasonable possibility that the compared materials are either identical or sufficiently similar; and therefore, whatever differences in potential effects might exist, are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence is shifted to Applicant. Applicant has not met that on the record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

V. Afremova

May 11, 2004

VERA AFREMOVA

PATENT EXAMINER